

SOLVE CFS

The Chronicle of the CFIDS Association of America

Fall 2009

Association Tightens Research Focus

In November 2007, the Association announced a major expansion of its internal research capacity when systems biologist **Dr. Suzanne Vernon** joined our staff as Scientific Director. Our Board of Directors evaluated our strategic direction and established a new focus for our research program: to build, support and link a critical mass of innovative and credible researchers focused on early detection, objective diagnosis and effective treatment and to create, identify and leverage new private and federal funding sources and opportunities for CFS investigators.

In March 2008, we issued a request for applications and reviewed 24 responses from research groups around the world for scientific and strategic merit. We announced funding for six innovative studies in November 2008 and in January 2009 we initiated the first formal CFS research network. The network established a stronger foundation with the Banbury meeting held in partnership with the **National Institutes of Health (NIH)** in September 2009. We're now working with the **Biological Informatics Research Network**, an NIH-sponsored initiative, to develop the infrastructure to support participation

of multiple sites and investigators in pooling data and developing best practices and standard operating procedures to bring greater cohesion to the field of CFS research. We have also joined the Genetic Alliance, a coalition of more than 600 disease advocacy organizations. We now have access to its resources that enable advocacy organizations to be more effective research-support organizations.

To expand the pool of funds available to support CFS research, we responded to four federal funding opportunities made available under the **American Recovery and Reinvestment Act (ARRA)**, with several additional proposals under development. Some of our funded investigators are co-applicants on these proposals and others have submitted independent applications to sustain their studies. We will eagerly share news of new awards as soon as possible.

With these activities under way and the promising discovery of XMRV, there has never been greater potential for accelerated progress in CFS research. We hope this research-focused issue of *SolveCFS* adequately conveys that sense of optimism and opportunity. ■

XMRV Study Attracts Worldwide Attention

In the Oct. 8, 2009 issue of *Science Express*, researchers at the **Whittemore Peterson Institute (WPI)**, the **Cleveland Clinic** and the **National Cancer Institute (NCI)** reported that 67% of 101 chronic fatigue syndrome (CFS) patients tested positive for infection with xenotropic murine retrovirus (XMRV), a gammaretrovirus previously associated with a subset of aggressive prostate cancer tumors. Only 3.7% of 218 healthy subjects tested were positive for the virus. The study attracted international coverage from top media outlets including the *New York Times*, *Wall Street Journal*, *Nature*, *The Scientist*, National Public Radio, BBC, and hundreds of other publications and broadcast stations.

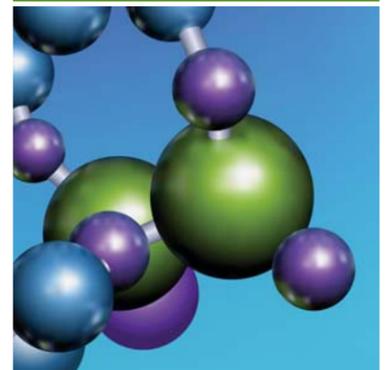
According to supplementary material published in the same issue of *Science*, the CFS patients in the study were classified as having CFS using both the 1994 research case definition and the 2003 Canadian clinical definition. The subjects were selected from

regions around the country where CFS clusters occurred and all had documented immune system abnormalities and exercise testing impairments.

These results provide evidence of the association of at least a subset of CFS cases with retroviruses, a hypothesis formed in the mid-1980s and pursued by several independent research groups with support from the CFIDS Association of America.

At the end of the article, the study authors raise questions about the discovery, including "Is XMRV infection a causal factor in the pathogenesis of CFS or a passenger virus in the immunosuppressed CFS patient population?" This question and others warrant additional investigation and the replication of this study's findings in other patient cohorts should be a priority for the field.

The CFIDS Association of America congratulates Dr. Judy Mikovits and her team at the Whittemore Peterson Institute and their collaborators at the Cleveland Clinic and NCI for this landmark discovery. This discovery and its publication in a journal of the stature and circulation of *Science* is a highly significant contribution to the field. This study, the high-profile publication, and the international media attention it has generated are important validation of the reality and seriousness of CFS. ■



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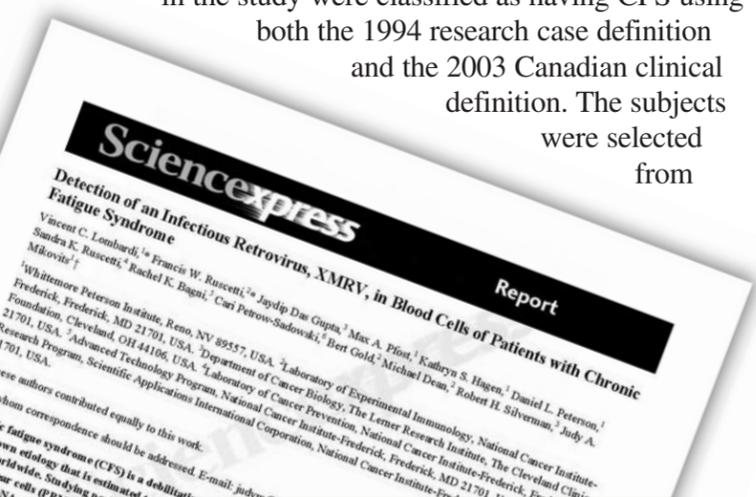
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Validate. Innovate. Eliminate.

Banbury Meeting: Productive Dialogue, Promising Outcomes



Tucked into a cove on Long Island's north shore, five miles from the **Cold Spring Harbor Laboratory**, is the pastoral **Banbury Conference Center**. The Banbury Center is located on an estate that was given to Cold Spring Harbor Laboratory in 1976 and is acknowledged internationally to be a superb venue for small scientific meetings. Since opening, over 11,000 scientists — including 41 Nobel laureates — have attended meetings at the Banbury Center. Three stately residences house 35 guests for invitation-only meetings on diverse topics in molecular biology, molecular genetics, human genetics, neuroscience and science policy. The Association's scientific director, **Dr. Suzanne Vernon**, had planned four Banbury meetings for the Centers for Disease Control & Prevention (CDC) and had attended two others there. She well understood the center's reputation for "promoting new ways of looking at problems, new lines of research and new collaborations" and believed this was the ideal setting to convene the Association's funded investigators for their second meeting of 2009.

Last year at Suzanne's request, Banbury Center director **Dr. Jan Witkowski** approved CFS as a meeting topic and together they submitted a grant to the NIH to fund this meeting. The grant application received highly favorable scores from peer reviewers and was funded, providing enhanced credibility (and valuable financial support) to the gathering. Funding was provided by the **National Institute of Neurological Disorders and Stroke (NINDS)**, **NIH's Office of Research on Women's Health (ORWH)** and the **CFIDS Association of America**. **Dr. Eleanor Hanna** of ORWH helped secure funding and shaped the agenda and guest list. Suzanne began planning and

asked researchers funded by the Association and NIH to reserve the meeting dates; a handful of experts representing other key research disciplines were also invited to attend.

The meeting, "**From Infection to Metabolism: A Nexus for CFS**," was held at Banbury Center from September 13 to 16, 2009. Strict confidentiality policies restrict any publication of details about individual presentations, which are treated as "personal communications," to foster sharing of unpublished data and interim analyses. In light of these restrictions, we'll convey a sense of the meeting itself and its expected outcomes in guiding research on CFS.

The meeting had three stated objectives:

1. To have funded CFS investigators present their latest research;
2. To identify common interests and study synergies; and,
3. To coordinate funded investigators into an expanded CFS research network.

Sessions were organized into the following general categories: gathering and integration of data for identifying biomarkers for CFS diagnosis and treatment; infectious and immunologic biomarkers of CFS; autonomic nervous system and central nervous system biomarkers of CFS; future directions; and implementing a CFS research network. Participants delivered 20-minute presentations followed by 10 minutes of critical questions and spirited discussion, an essential feature unique to this style of meeting that is difficult to replicate at large scientific conferences. Debates that began in the conference center continued around the dinner table and on walks between venues through the secluded waterfront property.

A small working group of subject matter experts and stakeholders met between the formal sessions to evaluate evidence, suggest paths forward and review points raised during discussions. On the final morning, this group presented its recommendations.

There was broad consensus that a CFS network was essential to accelerate progress and that the CFIDS Association and NIH should collaborate to leverage existing expertise from successful network models like NIH's

Biomedical Informatics Research Network and the National Cancer Institute's **Early Detection Research Network**. This CFS network would impact research and patient care, bringing clinical and academic investigators into closer contact and stronger alignment.

The meeting ended with unparalleled enthusiasm and collegiality for uniting studies and using new tools to deepen insights and advance understanding of CFS.

Suzanne is executing the agreed upon action steps from the meeting, and fostering connections between investigators that were begun at the Banbury meeting. We are also incorporating the network concept into our policy work with **B&D Consulting** to inform Capitol Hill about this promising direction, strengthen support from NIH, and secure access to CFS data collected by researchers at the CDC. You can be sure that you'll be hearing more about the CFS research network in the coming months as plans progress! Visit www.cfids.org/SolveCFS/fall09.asp for updates. ■



Banbury's Dr. Jan Witkowski welcomes the group.



The working group summarizes after day two.

As envisioned during the final session at Banbury, a CFS network could be utilized to:

- Engage talented investigators making promising advances in diagnosing CFS and understanding its underlying mechanisms;
- Expand communication among funded investigators;
- Promote enhanced information and data sharing and advanced methods of data analysis;
- Develop standard operating procedures for sample collection, storage and processing and standard protocols for various challenge tests to aid in comparability across research sites;
- Provide assistance to new and/or less experienced investigators; and
- Pool data to better understand natural history and identify biomarkers.



NIH's Dr. Eleanor Hanna (center) with Kim McCleary and Dr. Suzanne Vernon of the CFIDS Association.

Association-Funded Researchers Making Headway

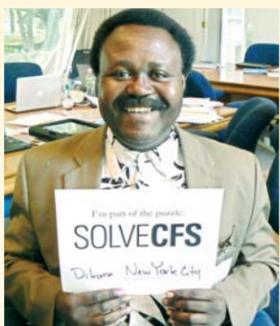
by Suzanne D. Vernon, PhD, Scientific Director, The CFIDS Association of America

In March 2008, the CFIDS Association issued a funding opportunity announcement for studies of biomarkers for early detection, objective diagnosis and treatment of CFS. Following a thorough peer-review process and evaluation of the top proposals' strategic merits, funding for six research studies was announced in November 2008. All six teams of investigators have hit the ground running. Here are some current highlights:



Drs. Kathy and Alan Light and their **University of Utah** research team are looking for objective diagnostic markers of CFS. Earlier this summer, the Light team published new findings

in the *Journal of Pain* describing blood-based markers that appear linked to symptoms of fatigue and pain in CFS. They are detecting receptors specific to metabolites created by the muscles during a moderate exercise challenge. What is notable is that the markers are not present when CFS subjects are at rest. However, after moderate exercise on a stationary bicycle, the expression of these markers on blood cells increases dramatically in CFS subjects, but not in healthy controls or patients with multiple sclerosis (another condition with substantial pain and fatigue) who exercise the very same way. This means that — so far — these markers appear to detect the post-exertion fatigue that is the hallmark of CFS. A diagram illustrating the difference in the markers appeared on the cover of the October 2009 issue of the *Journal of Pain*. The Light team is testing more CFS subjects and other disease control groups to determine just how specific these markers are to CFS. If it pans out, this may be the first objective diagnostic blood test for the hallmark symptom of post-exertion fatigue in CFS.



Dr. Dikoma Shungu at **Weill Cornell Medical College** and his collaborators continue to examine brain metabolism in CFS. Earlier in the year, Shungu and his team published a

paper in a prestigious imaging journal, *NMR in Biomedicine*, describing increased lactate levels in the brain cerebrospinal fluid of CFS patients. Elevated brain lactate is an indication of metabolic disturbance in CFS. It is notable that this was not found in the healthy control and disease control (generalized anxiety disorder) comparison groups tested. With their current award from the CFIDS Association, Shungu has extended the study to include more CFS subjects and a major depressive disorder disease control group. An exciting aspect of this study is that these subjects will also participate in Dr. Marvin Medow's study (below). This pair of investigative teams has developed a model that is based on infection causing inflammation and oxidative stress that alters blood flow and increases brain lactate. Elevated lactate can be detected by MRS, a non-invasive imaging

test. This could be an important approach to detect CFS early in the course of illness, important since the earlier CFS is detected and diagnosed, the greater the chance of effective intervention.



Dr. Marvin Medow and his team at **New York Medical College** study postural tachycardia syndrome (POTS), a chronic form of orthostatic intolerance associated

with signs and symptoms of lightheadedness, loss of vision, headache, fatigue, and neurocognitive deficits. Many young people with CFS also have POTS, and at least half of adults with CFS have POTS. Medow studies whether these POTS symptoms are due to reduced brain blood flow. He and his team published a paper in August 2009 describing decreased brain blood flow and altered regulation of blood flow by the brain in POTS patients. Medow and his team continue to study why blood flow is altered in CFS patients with POTS and are examining chemicals in the body that cause oxidative stress and molecules that affect the function of blood vessels. Subjects that participate in the Medow study also participate in the Shungu study described above. This will allow the Medow findings on blood flow mechanisms in the body to be related to the blood flow and metabolic alterations that Shungu is finding in the brains of CFS patients. This type of integrated study of blood flow and metabolic alterations has the potential to improve CFS treatment.



Dr. Gordon Broderick of the **University of Alberta** has been working with colleagues at Northwestern University and University of Illinois-Chicago

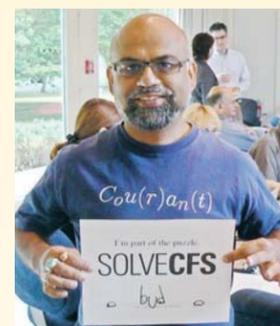
to understand how Epstein-Barr virus (EBV) can trigger CFS following infectious mononucleosis. Broderick is a systems biologist who uses sophisticated mathematical approaches and powerful computers to construct models of CFS based on actual clinical and laboratory data. He has published several papers over the past year that model how the brain, endocrine system, and immune system are altered in people with CFS. A figure from one of his papers recently made the cover of the journal *Genomics*. When he is not in his laboratory, Broderick teaches medical students about computational biology and

uses examples of CFS in many of his lectures. Broderick recruited five medical students to conduct research in his group with the objective of raising awareness of CFS and CFS research among tomorrow's clinicians. In addition to getting exposure in the media, the medical students have published two articles in the peer-reviewed literature.



Dr. Sanjay Shukla of the **Marshfield Clinic Research Foundation** will study gut microbes in CFS. We now

know that humans require the right kind and the right balance of microbes in our intestines to stay healthy. Shukla hypothesizes that people with CFS do not have the right kind and balance of microbes and that exertion causes the microbes to leak across the intestine causing inflammation and metabolic disturbance. He has assembled a team of experts in internal medicine, exercise physiology and bacterial phylogeny to assist him in this innovative study. The team has begun enrolling patients and controls and will collect blood and stool samples before and after an exercise challenge to study how exertion affects gut function and ecology. Stay tuned to what are certain to be interesting and important results that could impact the diagnosis and treatment of CFS.



Professor Bud Mishra and his bioinformatics team at **New York University** will use computer software they developed to identify subtypes and possible causes of CFS. Mishra and

his team are compiling medical records from hundreds of well-characterized CFS patients to accomplish this. Once the medical records have been converted to an electronic form and then "read" by the computer, a team of human experts will evaluate how well the computer has interpreted the information. Sound futuristic? Perhaps, but the reality is that using computers to process large records and search for patterns is a smart application of "artificial intelligence." Many people with CFS have huge binders for their medical records. Mishra's team is essentially searching medical records from hundreds of CFS patients to identify CFS subtypes and causes. Think of this project as a highly specific application of Google-like technology that will identify new information and translate it for use in clinical settings. ■

Xplained

by Suzanne D. Vernon, PhD, Scientific Director,
The CFIDS Association of America

The announcement on October 8, 2009, that an infectious retrovirus called XMRV (xenotropic murine-related retrovirus) was linked to CFS, could be the game-changing scientific event we have been waiting for. Whether XMRV provides the long-awaited causal link will depend on the findings described in the *Science* paper being replicated by another laboratory in another group of CFS patients. To help clarify what we know, let's review the findings.

Dr. Judy Mikovits and her team at the Whittemore Peterson Institute for Neuro-immune Disorders (WPI) made a very insightful connection three years ago. XMRV was first described in prostate cancer in 2007 by investigators at the Cleveland Clinic, who also reported that XMRV-positive prostate cancer patients have alterations in RNase L, an antiviral immune system pathway. The WPI investigators knew that RNase L activity is also altered in blood cells from CFS patients and they made the decision to look for XMRV in CFS patients with this immune defect.

When scientists want to find a virus, we look for it in the sickest individuals because often this is where there is likely to be the highest levels of a virus, if present. Dr. Dan Peterson has been caring for and researching CFS patients since the 1984 Incline Village outbreak, so he identified CFS patients with prolonged disabling fatigue, cognitive impairment, and documented laboratory immunological abnormalities (including altered RNase L activity) to hunt for XMRV.

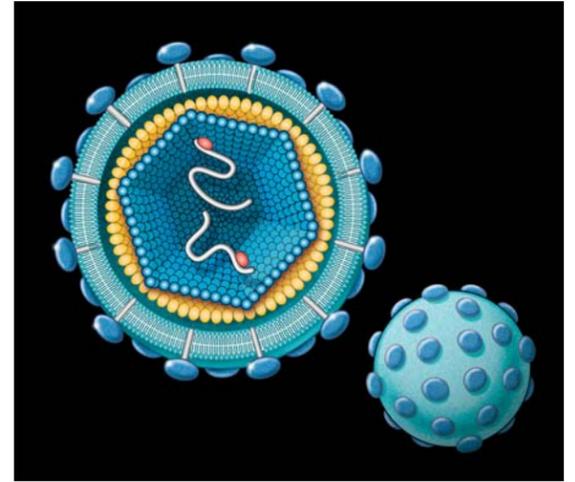
The WPI laboratory team detected XMRV sequences in 68 of 101 (67%) CFS patients tested and in 8 of 218 (3.7%) healthy control subjects. The Cleveland Clinic confirmed the presence of XMRV in a subset of these same CFS cases, 7 of the 11 (64%) samples from

WPI. The Cleveland Clinic researchers found that the CFS XMRV was similar to prostate cancer XMRV, and not a mouse virus (murine leukemia virus) that could have been a contaminant explaining the discovery.

The investigators designed several laboratory tests to understand XMRV. They looked to see if XMRV was expressed in peripheral blood mononuclear cells (PBMCs) of CFS patients. PBMCs circulate throughout the entire system and can be important "sentinels" for processes occurring in the body. PBMCs from 19 of 30 CFS patients expressed XMRV proteins compared to 0 of 16 PBMC samples from healthy controls. They also wanted to know which cells harbored XMRV; they found it in T and B cells in the blood of one CFS patient. The investigators looked to see if the XMRV from CFS patients was infectious. Both blood cells and plasma (the cell-free fraction of blood) from XMRV-positive CFS patients were able to transmit this virus to a susceptible cell line, indicating infectiousness in laboratory culture. Finally, they wanted to know if XMRV stimulated the immune system to produce antibodies. Plasma from 9 of 18 CFS patients had antibodies that reacted with a virus protein similar to that found in XMRV, compared to no reaction from plasma of 7 healthy controls.

This *Science* paper tells us that XMRV plays a possible role in CFS pathogenesis in these CFS patients. How much we can generalize these findings to other CFS patient populations? That answer will depend on the results of replication studies.

The design of replication studies should include CFS patients who are similar to those reported in the *Science* study. Dr. Peterson reported at the Oct. 29 CFS Advisory Committee meeting that the 101 patients in the study were drawn from CFS practitioners in Nev., Calif., Ore., Fla., N.C., and N.Y. They ranged in age from 19 to 75 with a mean age of 55. Sixty-seven percent were



Cross-section of XMRV provided by Robert H. Silverman, Ph.D., Lerner Research Institute, Cleveland Clinic, illustration by David Schumick, BS, CMI and Joseph Pangrace, BFA, CMI. Reprinted with the permission of the Cleveland Clinic Center for Medical Art & Photography © 2009. All Rights Reserved.

female. The controls were age, sex, and zip-code matched and were not contacts of the patients studied, nor were they lab workers.

Methods used in independent replication studies should also follow the WPI protocol and use similar reagents. We are actively working with several independent research groups in the U.S. and other countries to expedite these studies.

While these exciting studies of XMRV continue, the CFIDS Association continues its support of our funded investigators. It's important to remember that HIV was discovered to be the cause of AIDS 26 years ago, but worldwide research on AIDS treatment, cure and prevention continues today. Our funded investigators' research on why Epstein-Barr triggers CFS, whether ion-channel receptors are markers of fatigue, why CFS patients have higher rates of leaky gut, why CFS patients have slow blood flow to the brain, why CFS patients have metabolic disturbances in the brain, and how we can bring this information, as well as XMRV, together using powerful computational tools are all important as we work together to solve CFS. ■

In light of the Oct. 8 publication by Lombardi et al in *Science* linking CFS and xenotropic murine-related retrovirus (XMRV), the CFIDS Association of America requested guidance from the National Cancer Institute about XMRV for persons diagnosed with CFS, their loved ones, and the general public. The following is an excerpt of the interim guidelines issued in a letter received from NCI director Dr. John E. Niederhuber. Check www.cfids.org/SolveCFS/fall09.asp for updates.

Interim XMRV Guidelines from National Cancer Institute



We at the National Cancer Institute (NCI) have great interest in these initial research findings. At present, we agree that a critical issue to be addressed is whether the exciting recent results obtained using samples from the Nevada cohort can be reproduced in additional cohorts of CFS-afflicted individuals. The NCI is striving to develop tools so that the general prevalence of XMRV in the population can be ascertained, and the association of XMRV with disease can be examined.

In the meantime, it is very important to reiterate what we do not know at this point, specifically:

1. We do **not** know whether XMRV is a causative agent for CFS, prostate cancer, or any other disease. Even if a causal

association can be established, it may be only one of many causes, and there may be other factors, genetic or environmental, that determine the outcome of infection. At the moment, there is no evidence of CFS transmission between family members, even though XMRV appears to be an infectious agent. Thus, it is unclear whether XMRV alone underlies CFS.

2. We do **not** know how XMRV is transmitted from individual to individual. Recent suggestions of sexual or salivary transmission are not based on direct evidence, and conclusions regarding transmission are not credible at this point. Given the frequent isolation of virus from white blood cells, blood-borne transmission is a real possibility, and, while we are not in a position to establish firm guidelines, prudence would dictate that

potentially infected individuals refrain from blood donation at this time.

3. We do **not** know how many apparently healthy individuals are infected, and what the distribution of infection is within the U.S. and in the worldwide population. The National Cancer Institute is involved in coordinating a global effort to study these issues.

It is very important to keep in mind that there is no evidence for a new increasing or spreading XMRV infection. Further, no credible evidence exists for direct transmission of either CFS or prostate cancer.

John E. Niederhuber, M.D.
Director, National Cancer Institute
U.S. National Institutes of Health
Department of Health and Human Services
October 23, 2009



Looking Back, Looking Ahead

by Suzanne D. Vernon, PhD, Scientific Director,
The CFIDS Association of America

November 1, 2009 marked my two-year anniversary as scientific director for the CFIDS

Association of America. Of the twelve years I have been working to solve CFS, these past two have been the most challenging, exciting, and rewarding of my professional career. *Challenging* because we have strategically realigned ourselves to be the largest CFS advocacy and research support organization in the U.S. *Exciting* because we have funded investigators who are researching and discovering markers that will increase the likelihood of early detection, provide means for objective diagnosis, and refine approaches to treatment. *Rewarding* because we lead advocacy and research support efforts with integrity, innovation, and purpose. I will continue my dedication and commitment to make CFS widely understood, diagnosable, curable, and preventable by working with the Association for as long as it takes to achieve our mission.

I am also humbled. Because of your support we have been able to fund more than \$5 million of research looking for viral and bacterial causes of CFS, studying CFS immune dysfunction and RNase L abnormalities, and dysautonomia — to name a few of the many topics we've supported over the years. These studies have been spearheaded by top-notch scientists, many who are now known as leading CFS investigators in the world including: Drs. Anthony Komaroff, Daniel Peterson, and Nancy Klimas. In the late 1980s when retroviruses were prime suspects for CFS, the CFIDS Association provided more than \$400,000 in support to Dr. Elaine DeFries to study an HTLV-II like retrovirus. This was the first sighting of a retrovirus in people with CFS. The CFIDS Association has always understood the power of research, but it is you — our fervent supporters — who have entrusted us with making this

research possible. It is you who are to be congratulated for investing wisely. You have helped us create a strong foundation of research and researchers and now, in light of the XMRV discovery, we are perfectly poised to expand our support of research.

Many readers may not realize the incredibly competitive and political nature of science. To most of the CFS medical and research community, the XMRV finding published in *Science* was a surprise announcement. While many investigators were cautiously optimistic and excited about how this could be a game-changing finding, some were ready to “pack up and go home” — mostly because the media blitz read like a “case closed” Sherlock Holmes novel. It takes only a brief review of lessons learned from other remarkable discoveries like HIV to understand that detecting a virus is the beginning. If the XMRV finding is replicated in other CFS populations, validated to be the cause of CFS, and the FDA approves XMRV as a diagnostic test for CFS, then we can “check off” objective diagnosis from our to-do list! XMRV is a new beginning, not the end.

Personally, I hope XMRV is validated and found to have a role in CFS — finally we will have a context for all the important and remarkable ongoing research. And in no way does XMRV reduce the importance of ongoing research on immune dysfunction, other pathogens, post-infection fatigue, dysautonomia, HPA axis dysfunction, oxidative stress, and altered neurometabolism, etc. On the contrary, it gives these investigators a strategic advantage and a competitive edge for CFS funding opportunities that will advance treatment and prevention.

The next two years promise to be more challenging, exciting, and rewarding than the past two — not just for me, but for all of us. Thank you for your continued support, investment, and trust. ■

H1N1 Pandemic & CFS

The influenza-A virus type H1N1 is a fixture in the media headlines and continues to generate questions from the CFS community.

The H1N1 flu virus contains genes from flu viruses from pigs, birds, and humans and was initially known as “swine” flu. It is new and unfamiliar to our immune systems, making it easier for this flu virus to make people sick and spread. Unlike most other flu strains, H1N1 is impacting younger people. Flu viruses spread by aerosol, the spray generated from a sneeze or cough. Try to not touch your eyes, nose, and mouth and regularly wash your hands, especially after coughing or sneezing.

If flu-like illness is circulating in your community, stay home. Minimize trips to public places where exposure risk might be greater. If you get sick, stay home for seven days after your symptoms begin or until you have been symptom-free for 24 hours.

Flu viruses take a toll on people who have medical conditions such as asthma or immune deficiencies. CFS sufferers may also be at increased risk of complications from H1N1 flu. Reports from CFS patients who have had H1N1 are mixed, with some people reporting extended relapse following the flu and others stating that it was a relatively mild five-day illness with some intensification of their CFS symptoms. The first case of CFS following H1N1 infection was reported in the October 2009 issue of the *Journal of Clinical Pathology*, by Dr. Ros Vallings of New Zealand. The CFIDS Association and the IACFS/ME have asked CDC to prioritize post-flu CFS in the agency's surveillance program. So far, no one has reported unusual difficulties among CFS patients taking Tamiflu.

Regarding the H1N1 vaccine, some patients with CFS report more complications following routine vaccinations and recommendations for persons with CFS vary among experts. People who have had past problems following vaccine administration are generally advised not to get the H1N1 vaccine.

Links to H1N1 resources: www.cfids.org/SolveCFS/fall09.asp. ■

Testing for XMRV

In the weeks since the *Science* publication, two commercial laboratories have begun promoting XMRV



tests. The first to market was

Cooperative Diagnostics (www.codiagnosics.com), a S.C. company, with a DNA-based home test kit that costs \$399. The company states that it is not affiliated with the Whittemore Peterson Institute and discloses that test results can only be interpreted by a physician and that costs will not be reimbursed by insurance.

RedLabs USA. VIP Dx is marketing PCR and culture tests (\$400 and \$500, respectively, or \$650 for both) performed using the same methods as were reported in the *Science* article. The website discloses that the tests have not been approved by FDA for diagnostic purposes and that medical expertise is required for test interpretation.

Experts have expressed caution regarding new tests for XMRV. In his Nov. 3 *Lyndonville Times* newsletter, **Dr. David Bell** provided the following guidance, “I am reluctant to suggest to anyone that they spend big bucks for a commercial test now. We do not know if a particular test is accurate, and even if it is accurate we do not know what it means, and even if we did know what it meant we would not know what to do with it. I would be patient. Answers will start flowing soon, so stay tuned!”

Speaking at the Oct. 29, 2009 meeting of the CFS Advisory Committee (*see page 6*),

retrovirology expert **Dr. John Coffin** reported that the National Cancer Institute (NCI) is working intently to develop assays using validated specimens so that “everybody is on the same page, using the same assays for this virus.”

A letter from NCI director **Dr. John Niederhuber** (*see page 4*) to the Association reiterates his institute's commitment to test development. “We are taking a proactive approach to...developing suitable, well-validated assays to detect XMRV infections.”

Certified laboratories can market tests with little regulation by federal agencies; however, diagnostic tests for conditions and diseases are subject to review and approval by the Food and Drug Administration before they can be marketed as such. Insurance companies' reimbursement policies vary, however without FDA approval, it may be challenging to obtain coverage for the XMRV tests now on the market. ■



The second test to market is offered by **VIP Diagnostics** (www.VIPdx.com), a Nevada company owned by the Whittemore family, formerly known as

CFS Advisory Committee Holds Timely Session

In the “Great Hall” of the Department of Health and Human Services building in Washington, D.C., the federal CFS Advisory Committee (CFSAC) held its 16th semi-annual meeting on Oct. 29–30, 2009. Usually a quiet, sparsely attended session held in the 8th floor conference room, by contrast this meeting was illuminated by banks of bright lights, three hulking video cameras, about 100 observers, and a meaty agenda. Three weeks prior, researchers from the Whittemore Peterson Institute (WPI) had broken new scientific ground with a high-profile paper linking CFS and XMRV. The WPI’s discovery set the stage for fascinating presentations by **Dr. Daniel Peterson** and **Dr. John Coffin** (a National Academy of Sciences member considered widely as a world authority on retroviruses), passionate public testimony, and spirited recommendations to the Secretary of Health over the two days. Designated federal official, **Dr. Wanda Jones**, and chairman **Dr. James Oleske** led the meeting.

You can find links to a comprehensive meeting report, NIH’s archived videocast

of the entire meeting, and other presentations and testimony at www.cfids.org/SolveCFS/fall09.asp.

COMMITTEE RECOMMENDATIONS

In the last session of the day, Committee members debated and revised formal recommendations to the Secretary of Health. These four passed by unanimous votes.

Recommendation 1: The CFSAC renews its recommendation to the Secretary to establish Centers of Excellence for CFS that would effectively utilize state of the art knowledge concerning the diagnosis, clinical management, treatment, and clinical research.

Recommendation 2: The CFSAC renews its recommendation to the Secretary, as submitted 6 months ago, to establish progressive leadership at the CDC. It is disappointed that no response has been made to the earlier recommendation and it is interested in getting feedback, especially in light of the comments made to the *New York Times* by Dr. Reeves that reflect an inappropriate bias and undermine others’ CFS research.

Recommendation 3: The CFSAC objects to CDC’s continued use of the inadequate and inappropriate 2005 “empiric” research definition for CFS. It recommends that CDC abandon the empiric case definition and the fundamentally incorrect conceptualization of chronic unwellness as being equivalent to CFS incorrect.

Recommendation 4: The CFSAC has significant concerns about the CDC’s five-year plan. In particular, the priorities articulated in its recommendation of May 2009 have not been adequately captured in the latest draft. The CFSAC renews its recommendation that CDC prioritize: identification of biomarkers and (viral) etiology of CFS; partnership with organizations representing CFS scientific expertise to create guidelines for adult and pediatric management; provide web-based guidelines for CFS management given our current state of knowledge and expert opinion; and provide comprehensive information about CFS in partnership with CFS experts to the scientific community, medical and mental health providers, educational institutions, and the public for both adult and pediatric CFS through DHHS resources. ■



Testimony Before the CFS Advisory Committee on October 29, 2009

by K. Kimberly McCleary, President & CEO, The CFIDS Association of America

I am grateful for this timely opportunity to address members of the CFS Advisory Committee, the ex-officio agency representatives and the public — here and viewing the videocast. I believe I hold the unique distinction of having attended every single meeting of this committee and its predecessors since they were first opened to the public in 1993. This morning’s session was the best session of this committee in my memory. I extend gratitude to Dr. Wanda Jones for inviting Dr. Dan Peterson and Dr. John Coffin to address the committee and the public on the important XMRV research.

A lot has happened since that first open meeting 1993, and at the same time, too little has happened. In fact, a lot has happened since the most recent CFSAC meeting in May, and (again) too little has happened.

Since 1993 a few facts have been documented beyond dispute. CFS is a very real condition and it seriously affects the lives of millions of people worldwide who have it, and people who love those who have it. CFS is complicated. Whether it’s caused by a retrovirus called XMRV or it is the result of multiple genetic and environmental factors, including one or more agents acting together, it has defied explanation for a quarter of a century.

What we knew in 1993 and what we know today is that we need more research. We need better medical care. We need more people — especially doctors — to understand and to care about CFS.

But what has stumped this panel of CFS experts and all of us who have taken part as advocates over the years is how to mobilize

our federal resources to accomplish those things. There is now the scientific momentum to fuel mobilization.

Notably, the National Institutes of Health has participated in the XMRV research through the National Cancer Institute’s intramural program and the National Institute of Allergy and Infectious Diseases recent grant to the Whittemore Peterson Institute to support expanded research on XMRV. NCI director Dr. John Niederhuber has reiterated his institute’s support of continued research on this topic to understand the relationship of XMRV to human disease, including CFS and prostate cancer. He also provided very helpful interim guidelines (*see page 4*), at the Association’s request, to help patients, family members, and the public while this research expands.

In addition, the NIH’s Office of Research on Women’s Health collaborated with the CFIDS Association to host a meeting of funded investigators last month at Cold Spring Harbor Laboratory’s Banbury Center (*see page 2*), with the outcome of unparalleled consensus that a formal research network linking CFS investigators would propel the field through enhanced communication, establishment of best practices, and implementation of standardized operating procedures for CFS studies. The XMRV research, and many of the issues discussed after the lunch break, could be immediately enhanced if this network existed. We are moving forward to implement recommendations arising from the Banbury conference to create this network. In the meantime, the CFIDS Association, like the WPI, is helping to coordinate with researchers in the U.S. and abroad who have genuine interest in replicating XMRV research.

In spite of this very recent progress, NIH funding for CFS is at the same level it was in

1993. There are many avenues of scientific investigation worthy of NIH support, and it is important not to lose sight of the many body systems affected by CFS that warrant continued study. We urge the CFSAC to recommend that NIH immediately issue an RFA to capitalize on increased interest in CFS research arising from the XMRV publication and the promise of a formal research network.

Six months ago when this committee met, the CDC presented a draft five-year strategic plan. The agency reports having received almost 1,200 “items of correspondence” about its draft by July 30. The final version distributed today incorporates some welcome additions, including recognition that the empiric criteria should be re-evaluated as the foundation for CDC’s research. However, the repetitive emphasis on psychosocial features, risk-conferring behaviors, and chronic unwellness reflects a disregard for and/or dismissal of the major criticisms of the draft plan loudly and plainly echoed by organizations and individuals at public meetings held in April, May and in written correspondence. I am reminded of the first public ICC meeting in 1993, held in Atlanta, at which federal agencies threatened to define CFS out of existence by eliminating the 11 symptom criteria and focusing solely on chronic fatigue. Now, this CDC plan imposes a similar death sentence. **We implore the CFSAC to aggressively challenge this plan to protect hard-earned progress** of the past 16 years and not waste \$25 million that should fuel important research.

In conclusion, the federal resources being applied to CFS must catch up with the magnitude of this condition, and must — at least — match the proportion of private investments. The momentum is building, and the time is now to solve CFS. ■

Like you, we've got big dreams.

A big vision.

A world free of the suffering caused by CFS.

CFS is a serious and complex illness, a puzzle that has defied being solved for a quarter of a century. Like most complex puzzles, the more people working on the problem, the more rapidly we'll identify the solution. Last year you helped expand our research program by enabling us to reach our \$1 million goal for the first phase of the Campaign to Accelerate CFS Research. Now we're building on that momentum and aiming even higher — to raise \$5 million by the end of 2010. These funds will support the Association's vital research and policy initiatives that will validate, innovate and, ultimately, eliminate CFS. The exciting XMRV discovery raises new questions that demand answers, and surfaces new needs that require solutions. In some ways, our work is just beginning. But hope for a healthier future has never been stronger.

To propel the SolveCFS campaign, we've launched a special website at www.SolveCFS.org. Watch our original video, "What Would You Do?" and learn what thousands of people with CFS told us they'd do tomorrow if they were completely well. Make a gift. Take a photo with the SolveCFS sign and add it to our online album. Engage others and encourage their support. Be part of the solution.

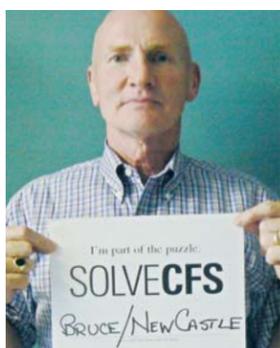
Together we can solve CFS.

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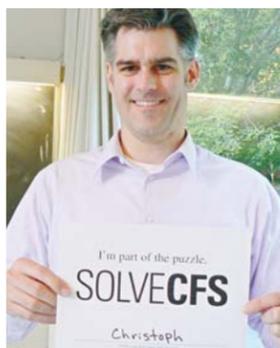


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Responses from 1,784 chronic fatigue syndrome patients to the question, "What would you do if you were completely well tomorrow?" Symptoms of CFS and ways you can help. You can be part of the solution; help us solve CFS. Brought to you by the CFIDS Association of America



Transitions on the Association's Board of Directors

Over the past 22 years, the CFIDS Association has been enriched by the leadership provided by 83 individuals who have contributed their "time, talent, and treasure" to shape and build this organization. They have brought varied perspectives, as persons with CFS, parents, close friends, and caregivers, and as professionals in fields relevant to the Association's work.



Susan Jacobs, Esq.

At the end of 2009, two directors will retire from Board service as they reach the six-year limit on directors' terms. **Susan Jacobs, Esq.**, who served as chairman 2005-2007, will be missed for the experience she brings from her legal training and service to other nonprofit boards. Susan was drawn to the cause by her former college roommate who was diagnosed with CFS in the mid-1990s.



Dr. Lynn Royster

Lynn Royster, J.D., Ph.D., will also retire at year-end. Lynn's adult son Patrick has been the inspiration for her service. In addition to

serving as chairman of several Board committees, Lynn served as vice chairman from 2005–2008. Among Lynn's many contributions was leading the effort to develop the Association's first written long-range strategic plan in 2005–2006.

Joining the Board in January will be three professionals with personal connections to CFS. **Diane Bean** is a member of the U.S. Foreign Service whose daughter Lauren has CFS. Diane previously served on the Board in 2005, although career demands forced her to step down before her term ended. She is eager to resume her service.

Vicki Boies, PsyD, and her husband Bill have been active supporters since 1995 out of concern for their daughter Carolyn, who has CFS. Vicki is a psychologist and has been active in several community organizations and with the Chronic Illness Initiative established by Lynn Royster at DePaul University.

Bob Raidt is a senior executive at Leo Burnett, an international consumer products advertising agency. Bob has extensive marketing experience as worldwide account head for McDonald's. Bob has worked with the March of Dimes in Chicago and has several connections to CFS that motivate his interest in serving. ■

New Addition to Our Staff

Ashley Comstock joined the Association's staff as our Major Gifts Officer in September. Ashley brings her development experience with the Alzheimer's Association and the American Diabetes Association to raise funds to expand critical research and policy efforts for CFS. ■

As We Went To Press...

The challenge of any print publication, no matter its frequency, is that it's outdated before readers receive it. A few current events were pending as this issue went to press. We've recapped here and will link to updates on our website at www.cfids.org/SolveCFS/fall09.

Outcomes from Several XMRV Validation Studies:

Independent research groups in the U.S. and other countries are currently testing samples from CFS patients and controls to look for active and latent XMRV infection.

Report from the HHS Blood Safety Committee:

Dr. Jerry Holmberg stated at the CFS Advisory Committee that the department's Blood Safety Committee meeting would be investigating the safety of the worldwide blood supply in response to reports that 4 percent of a small number of healthy control subjects had antibodies to the virus XMRV.

More Delays for Ampligen Application: The drug's manufacturer announced on Nov. 2 that it had filed additional required reports with the FDA and that more data was required to complete the application to market Ampligen for CFS. A decision is unlikely before year-end. ■

The CFIDS Association of America

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